BAUSCH & LOMB SURGICAL TECHNOLAS®217A EXCIMER LASER SYSTEM

LASER IN SITU KERATOMILEUSIS (LASIK) PROFESIONAL USE INFORMATION

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner. U.S. Federal Law restricts this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

This document provides information concerning the intended clinical use of the TECHNOLAS 217A Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the TECHNOLAS 217A Excimer Laser System *User Guide.*

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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SECTION 1

SAFETY CONSIDERATIONS

Gas Handling

The high-pressure gas cylinders should only be handled by service technicians professionally trained by Bausch & Lomb TECHNOLAS. Please refer to the TECHNOLAS 217A Excimer Laser System User Guide, Section 2, SAFETY CONSIDERATIONS.

Skin and Eye Exposure

The TECHNOLAS 217A Excimer Laser System contains a Class IV laser with an output at 193nm which is potentially hazardous to the skin and the surface layers of the cornea. For this reason, specific controls are required which prevent accidental exposure of laser energy to the eye and skin from both direct and reflected laser beams. In addition, precautions must be taken in the surgical area to prevent the hazards of fire and electrical injury. Please refer to the TECHNOLAS 217A Excimer Laser System User Guide, Section 2, SAFETY CONSIDERATIONS.

SECTION 2

DEVICE DESCRIPTION

The specifications for the TECHNOLAS 217A Excimer Laser System are provided below.

Laser Type:	Argon Fluoride
Laser Wavelength:	193 nanometers
Laser Pulse Duration:	18 nanoseconds
Laser Head Repetition Rate:	50 Hz
Effective Corneal Repetition Rate:	12.5 Hz
Fluence (at the eye):	120 mJ/cm^2
Range of Ablation Diameter:	2.0 to 2.05 mm

Features and Components of the Excimer Laser System:

Laser Unit	The laser unit consists of the laser head (discharge system), which contains the optical resonator and a discharge chamber, which is filled with a premix of argon, fluorine, and a buffer of other noble gases.
Control Unit	The control unit contains the personal computer that uses a software algorithm to calculate the number and location of laser pulses required to achieve the desired correction.
Tower Unit	The tower unit provides the stable holding construction for the optical system of the TECHNOLAS 217A Excimer Laser. The tower unit contains the optical elements that condition the laser beam to the appropriate characteristics. The tower also contains the visualization

	optics (the operating microscope) and the positioning and fixation optics for properly locating and monitoring the progress of the ablation. There is a distance of 21 cm ("working distance") between the focusing point on the cornea and the laser arm.
Operating Elements	The operating elements of the TECHNOLAS 217A Excimer Laser System consist of two joysticks for movement of the patient bed in all axes and other operating elements and external connectors.
Bed Unit and Chair	The bed unit allows for accurate positioning of the patient during the surgical procedure while the operating chair allows the surgeon to adjust his/her position at the operating microscope.

SECTION 3

INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EVENTS

3.1. INDICATIONS FOR USE

The Bausch & Lomb Surgical TECHNOLAS 217A Excimer Laser System is intended for use:

- In laser in situ keratomileusis (LASIK) treatments for the reduction or elimination of myopia between -1.00 and -7.00 D of sphere and less than -3.00 D of astigmatism at the spectacle plane.
- In patients with documented evidence of a change in manifest refraction of less than or equal to 0.50 diopters (in both cylinder and sphere components) for at least one year prior to the date of the pre-operative examination.
- In patients who are 21 years of age or older.

3.2. CONTRAINDICATIONS

LASIK surgery is contraindicated in:

- Patients with collagen vascular, autoimmune, or immunodeficiency diseases;
- Pregnant or nursing women;
- Patients with signs of keratoconus or any other condition that causes thinning of the cornea;
- Patients who are taking one or both of the following medications: isotretinoin (Accutane), or amiodarone hydrochloride (Cordarone).

3.3. WARNINGS

- The decision to perform LASIK surgery in patients with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status should be approached cautiously. The safety and effectiveness of the TECHNOLAS 217A Excimer Laser System has not been established in patients with these conditions.

- LASIK is not recommended in patients with a known history of *Herpes simplex* or *Herpes zoster*.

- LASIK is not recommended in patients whose preoperative corneal thickness would leave less than 250 microns of remaining non-ablated cornea following the laser treatment.

3.4. PRECAUTIONS

3.4.1. GENERAL

The effects of LASIK on visual performance under poor lighting conditions have not been determined. It is possible, following LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes.

The safety and effectiveness of the Bausch & Lomb Surgical TECHNOLAS 217A Excimer Laser System have not been established:

- In patients with unstable or worsening myopia or astigmatism

- In patients with diseased or abnormal corneas;

- In patients with previous surgery or injury to the center of the cornea where LASIK will be performed;

- In patients with corneal neovascularization within 1.0 mm of the ablation zone;

- In patients under 21 years of age;

- In patients taking hormone replacement therapy or antihistamines who may have delayed re-epithelialization of the cornea following surgery;

- In patients who are taking sumatripin (Imitrex) for migraine headaches;

- In patients with a history of glaucoma;

- In patients with refractive treatments >7.0 D of myopia and $\geq$ 3.0D of astigmatism;

- In patients whose preoperative corneal thickness resulted in the laser ablation approaching closer than 250 microns to the corneal endothelium;

- To avoid corneal ectasia, the posterior 250 micons (μm) of corneal stroma should not be violated by the laser or the microkeratome.

- Over the longer term (more than 6 months after surgery);

- In patients with a history of keloid formation;

- In patients with a tendency to form scars;

- No safety and effectiveness data exist for LASIK treatments above 7.00 D of sphere or for more than 3.00 D of astigmatism and there is insufficient data for LASIK treatment of astigmatism above 3.00 D with the TECHNOLAS 217A Excimer Laser System.

3.4.2. PATIENT SELECTION

Consideration should be given to the following in determining the appropriate patients for LASIK:

- Complete examination, including, but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil and a clear crystalline lens is essential.

- To obtain accurate refractive information, contact lens wearers must be examined after a period of not wearing contact lenses for at least 2 weeks for soft lenses and at least 3 weeks for hard (PMMA) and gas-permeable lenses. Prior to treatment and after at least 3 weeks of not wearing contact lenses, patients who wear rigid gas permeable or hard lenses must have 3 central keratometry readings and manifest refraction taken at one week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular.

- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should only be used with careful medical supervision or the patient should not undergo LASIK surgery.

- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.

- Baseline evaluation of patients requesting refractive surgery should be performed within 30 days of the LASIK surgery.

- The patient should have the ability to lie flat without difficulty.
- The patient should be able to fixate steadily and accurately for the duration of the LASIK procedure.
- The patient must be able to understand the surgery and give informed consent.
- The patient must be able to tolerate eye drops to numb the eye.
- The patient should be clearly informed of all alternatives for the correction of his/her myopia including, but not limited to, spectacles, contact lenses, and other refractive surgeries.

3.4.3. PROCEDURE

The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or to the crystalline lens. The area of potential hazard (Nominal Hazard Zone) for the production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist further than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance to the primary beam.

Prior to initiating the lamellar keratectomy portion of the surgery with the microkeratome, the physician should perform the fluence test to ensure that the laser is ready to deliver laser energy.

3.4.4. POST-PROCEDURE

A slit-lamp examination should be performed on postoperative day one and as needed thereafter to ensure that healing of the cornea is complete. After the one-day examination, the following examinations are recommended at a schedule of at least 1, 3, and 6 months:

- Uncorrected visual acuity (UCVA or VA-sc)
- Manifest refraction with best spectacle-corrected visual acuity (BSCVA or VA-cc)
- Intraocular pressure (IOP)
- Slip-lamp examination, including evaluation of corneal clarity and the condition of the flap.

3.5. ADVERSE EVENTS, COMPLICATIONS, AND PATIENT FINDINGS

3.5.1. ADVERSE EVENTS AND COMPLICATIONS

Table 1 presents all the cumulative key safety, adverse events, and complications for all treated eyes reported in the study.

Other events that did not occur in this study that could occur following LASIK include: corneal perforations, hyphemas, hypopyon, post-treatment lens abnormalities with vision loss, persistent corneal decompensation/edema, or cystoid macular edema.

Table 1
Cumulative Key Safety, Adverse Events, And Complications
All Treated Eyes

Key Safety, Adverse Events, & Complications	n/N (%)
Key Safety Events	
Loss of ≥ 2 lines BSCVA at 3 months or later	5/386 (1.3%)
Loss of > 2 lines BSCVA at 3 months or later	1/386 (0.3%)
BSCVA worse than 20/40 at 3 months or later	1/386 (0.3%)
BSCVA worse than 20/25 at 3 months or later if 20/20 or better preoperatively	1/372 (0.3%)
Haze ≥ trace with loss of BSCVA > 2 lines at 3 months or later	0/386 (0.0%)
Increased manifest refractive astigmatism > 2.0 D at 3 months or later†	0/110 (0.0%)
All Adverse Event Reports Other than Above at Any Postoperative Visits	
Corneal abrasion	1/386 (0.3%)
Corneal edema (bed) at > 1 month	1/386 (0.3%)
Folds in flap	2/386 (0.5%)
Misplaced, misaligned, loose flap, or free cap with loss of > 2 lines of BSCVA	3/386 (0.8%)
Procedure aborted	3/386 (0.8%)
Secondary surgical intervention other than excimer laser treatment	2/386 (0.5%)
Thin flap	3/386 (0.8%)
All Complications at Any Postoperative Visits	
Corneal edema at ≤ 1 month	20/386 (5.2%)
Corneal scarring	1/386 (0.3%)
Double vision	1/386 (0.3%)
Epithelial ingrowth	1/386 (0.3%)
Epithelium in the interface with loss ≤ 2 lines of BSCVA	19/386 (4.9%)
Folds in flap	22/386 (5.7%)
Haze	1/386 (0.3%)
Lamellar keratitis	1/386 (0.3%)
Overcorrection	1/386 (0.3%)
Peripheral corneal epithelial defect (on the flap)	3/386 (0.8%)
Size and shape of flap not as intended	1/386 (0.3%)
Striae in flap	13/386 (3.4%)
Stromal scar	1/386 (0.3%)
Undercorrection	2/386 (0.5%)

†For eyes treated for spherical myopia only

3.5.2. PATIENT FINDINGS

At each scheduled postoperative visit, patients were asked to complete a questionnaire that allowed them to report any findings they had regarding their vision or ocular comfort following the surgery. Results for the subjective responses to these questionnaires at 6 months postoperative are provided in Tables 2a and 2b. These tables present the changes in each reported finding compared to the baseline value for that finding for all treated eyes.

Table 2A
Patient Findings Change from Baseline at 3 & 6 Months (1% to <10% Worse)
All Treated Eyes
(Sorted by Worse % at 6 Months)

Patient Findings	3 Months n/N (%)			6 Months n/N (%)		
	Better	No Change	Worse	Better	No Change	Worse
Redness	66/370 (17.8)	272/370 (73.5)	32/370 (8.6)	70/348 (20.1)	256/348 (73.6)	22/348 (6.3)
Variation of vision in bright light	37/370 (10.0)	304/370 (82.2)	29/370 (7.8)	31/348 (8.9)	295/348 (84.8)	22/348 (6.3)
Gritty feeling	42/370 (11.4)	301/370 (81.4)	27/370 (7.3)	45/348 (12.9)	282/348 (81.0)	21/348 (6.0)
Variation of vision in normal light	11/370 (3.0)	323/370 (87.3)	36/370 (9.7)	14/348 (4.0)	314/348 (90.2)	20/348 (5.7)
Burning	36/370 (9.7)	301/370 (81.4)	33/370 (8.9)	42/348 (12.1)	291/348 (83.6)	15/348 (4.3)
Double vision	6/370 (1.6)	356/370 (96.2)	8/370 (2.2)	10/348 (2.9)	329/348 (94.5)	9/348 (2.6)
Ghost images	4/370 (1.1)	357/370 (96.5)	9/370 (2.4)	4/348 (1.1)	336/348 (96.6)	8/348 (2.3)
Pain	16/370 (4.3)	332/370 (89.7)	22/370 (5.9)	16/348 (4.6)	325/348 (93.4)	7/348 (2.0)
Tearing	43/370 (11.6)	312/370 (84.3)	15/370 (4.1)	43/348 (12.4)	298/348 (85.6)	7/348 (2.0)
Headaches	65/370 (17.6)	291/370 (78.6)	14/370 (3.8)	63/348 (18.1)	278/348 (79.9)	7/348 (2.0)

N = Number of Self-evaluation Forms received with non-missing values at each visit.

Table 2B
Patient Findings Change from Baseline at 3 & 6 Months (≥ 10% Worse)
All Treated Eyes
(Sorted by Worse % at 6 Months)

Patient Findings	3 Months n/N (%)			6 Months n/N (%)		
	Better	No Change	Worse	Better	No Change	Worse
Halos	18/370 (4.9)	259/370 (70.0)	93/370 (25.1)	21/348 (6.0)	263/348 (75.6)	64/348 (18.4)
Dryness	73/370 (19.7)	221/370 (59.7)	76/370 (20.5)	98/348 (28.2)	191/348 (54.9)	59/348 (17.0)
Fluctuations of vision	24/370 (6.5)	286/370 (77.3)	60/370 (16.2)	26/348 (7.5)	271/348 (77.9)	51/348 (14.7)
Variation of vision in dim light	53/370 (14.3)	262/370 (70.8)	55/370 (14.9)	60/348 (17.2)	245/348 (70.4)	43/348 (12.4)
Night driving vision	75/370 (20.3)	244/370 (65.9)	51/370 (13.8)	79/348 (22.7)	229/348 (65.8)	40/348 (11.5)
Light sensitivity	77/370 (20.8)	239/370 (64.6)	54/370 (14.6)	80/348 (23.0)	230/348 (66.1)	38/348 (10.9)
Glare	39/370 (10.5)	272/370 (73.5)	59/370 (15.9)	38/348 (10.9)	274/348 (78.7)	36/348 (10.3)
Blurred vision	39/370 (10.5)	275/370 (74.3)	56/370 (15.1)	50/348 (14.4)	262/348 (75.3)	36/348 (10.3)

N = Number of Self-evaluation Forms received with non-missing values at each visit.

Those findings that were reported more frequently as having gotten worse compared to baseline than had gotten better compared to baseline included halos, ghost images, fluctuations of vision, and variation of vision in normal light. Itching was reported as worse than baseline in less than 1% of eyes at either 3 or 6 months after surgery.

SECTION 4

CLINICAL RESULTS

4.1. STUDY OBJECTIVES

A prospective, non-randomized, multicenter clinical study of 386 eyes was conducted to evaluate the safety and effectiveness of the TECHNOLAS 217A Excimer Laser System.

4.2. DATA ANALYSIS AND RESULTS

4.2.1 SAFETY AND EFFECTIVENESS RESULTS

Tables 3 and 4 present the summary of the key safety and effectiveness variables for the 386 eyes at all available postoperative visits for eyes treated for spherical myopia only and for astigmatic myopia, respectively.

Table 3
Summary of Key Safety and Effectiveness Variables
All Eyes Treated for Spherical Myopia Only

Key Safety & Effectiveness Variables	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)
Effectiveness Variables			
UCVA 20/20 or better*	81/100 (81.0%)	88/102 (86.3%)	79/92 (85.9%)
UCVA 20/40 or better*	100/100 (100.0%)	102/102 (100.0%)	92/92 (100.0%)
MRSE†, from Emmetropia, ± 0.50 D*	80/100 (80.0%)	89/102 (87.3%)	82/92 (89.1%)
MRSE†, from Emmetropia, ± 1.00 D*	99/100 (99.0%)	99/102 (97.1%)	92/92 (100.0%)
MRSE†, from Emmetropia, ± 2.00 D*	100/100 (100.0%)	102/102 (100.0%)	92/92 (100.0%)
Safety Variables			
Loss of ≥ 2 lines BSCVA	3/103 (2.9%)	2/105 (1.9%)	2/95 (2.1%)
Loss of > 2 lines BSCVA	0/103 (0.0%)	0/105 (0.0%)	0/95 (0.0%)
BSCVA worse than 20/40	0/103 (0.0%)	0/105 (0.0%)	0/95 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/101 (0.0%)	0/103 (0.0%)	0/93 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/103 (0.0%)	0/105 (0.0%)	0/95 (0.0%)
Increased manifest refractive astigmatism > 2.0 D‡	0/103 (0.0%)	0/105 (0.0%)	0/95 (0.0%)

N = Number of CRFs received with non-missing values at each visit.
* For all eyes minus those treated for monovision.
† MRSE = Manifest Spherical Equivalent = Manifest Sphere + 0.5 × Manifest Cylinder.
‡ For eyes treated for spherical myopia only.

Table 4
Summary of Key Safety and Effectiveness Variables
All Eyes Treated for Astigmatic Myopia

Key Safety & Effectiveness Variables	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)
Effectiveness Variables			
UCVA 20/20 or better*	205/253 (81.0%)	219/260 (84.2%)	223/254 (87.8%)
UCVA 20/40 or better*	253/253 (100.0%)	258/260 (99.2%)	253/254 (99.6%)
MRSE†, from Emmetropia, ± 0.50 D*	201/253 (79.4%)	213/260 (81.9%)	221/254 (87.0%)
MRSE†, from Emmetropia, ± 1.00 D*	246/253 (97.2%)	253/260 (97.3%)	252/254 (99.2%)
MRSE†, from Emmetropia, ± 2.00 D*	253/253 (100.0%)	260/260 (100.0%)	254/254 (100.0%)
Safety Variables			
Loss of ≥ 2 lines BSCVA	1/264 (0.4%)	2/271 (0.7%)	1/266 (0.4%)
Loss of > 2 lines BSCVA	0/264 (0.0%)	0/271 (0.0%)	0/266 (0.0%)
BSCVA worse than 20/40	0/264 (0.0%)	0/271 (0.0%)	0/266 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/254 (0.0%)	0/259 (0.0%)	0/254 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/264 (0.0%)	0/271 (0.0%)	0/266 (0.0%)
Increased manifest refractive astigmatism > 2.0 D‡	NA	NA	NA

N = Number of CRFs received with non-missing values at each visit.
* For all eyes minus those treated for monovision.
† MRSE = Manifest Spherical Equivalent = Manifest Sphere + 0.5 × Manifest Cylinder.
‡ For eyes treated for spherical myopia only.

4.2.2. SAFETY AND EFFECTIVENESS RESULTS AT THE POINT OF STABILITY

Tables 5 and 6 present the results for key safety and effectiveness at the point of refractive stability (3 months) stratified by the preoperative myopia.

Table 5
Summary of Key Safety and Effectiveness Variables at 3 Months (Stable Point)
Stratified By Preoperative MRSE*
Eyes Treated for Spherical Myopia Only

Key Safety & Effectiveness Variables	1.00 to 1.99 D n/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	4.00 to 4.99 D n/N (%)	5.00 to 5.99 D n/N (%)	6.00 to 7.00 D n/N (%)	> 7.00 D n/N (%)
Effectiveness Variables							
UCVA 20/20 or better†	9/9 (100.0%)	23/26 (88.5%)	11/15 (73.3%)	18/22 (81.8%)	19/19 (100.0%)	8/10 (80.0%)	0/1 (0.0%)
UCVA 20/40 or better†	9/9 (100.0%)	26/26 (100.0%)	15/15 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	10/10 (100.0%)	1/1 (100.0%)
MRSE*, from Emmetropia, ± 0.50 D†	7/9 (77.8%)	25/26 (96.2%)	11/15 (73.3%)	20/22 (90.9%)	17/19 (89.5%)	8/10 (80.0%)	1/1 (100.0%)
MRSE*, from Emmetropia, ± 1.00 D†	9/9 (100.0%)	26/26 (100.0%)	13/15 (86.7%)	22/22 (100.0%)	19/19 (100.0%)	9/10 (90.0%)	1/1 (100.0%)
MRSE*, from Emmetropia, ± 2.00 D†	9/9 (100.0%)	26/26 (100.0%)	15/15 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	10/10 (100.0%)	1/1 (100.0%)
Safety Variables							
Loss of ≥ 2 lines BSCVA	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	1/22 (4.5%)	1/19 (5.3%)	0/11 (0.0%)	0/1 (0.0%)
Loss of > 2 lines BSCVA	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)
BSCVA worse than 20/40	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/8 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/21 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)

N = Number of CRFs received with non-missing values at each visit.
* MRSE = Manifest Spherical Equivalent.
† For all eyes minus those treated for monovision
‡ For eyes treated for spherical myopia only.

Table 6
Summary of Key Safety and Effectiveness Variables at 3 Months (Stable Point)
Stratified By Preoperative MRSE*
Eyes Treated for Astigmatic Myopia

Key Safety & Effectiveness Variables	1.00 to 1.99 D n/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	4.00 to 4.99 D n/N (%)	5.00 to 5.99 D n/N (%)	6.00 to 7.00 D n/N (%)	> 7.00 D n/N (%)
UCVA 20/20 or better†	9/12 (75.0%)	43/47 (91.5%)	56/65 (86.2%)	50/59 (84.7%)	29/38 (76.3%)	23/30 (76.7%)	9/9 (100.0%)
UCVA 20/40 or better†	12/12 (100.0%)	47/47 (100.0%)	65/65 (100.0%)	58/59 (98.3%)	38/38 (100.0%)	29/30 (96.7%)	9/9 (100.0%)
MRSE*, from Emmetropia, ± 0.50 D†	9/12 (75.0%)	40/47 (85.1%)	56/65 (86.2%)	54/59 (91.5%)	29/38 (76.3%)	21/30 (70.0%)	4/9 (44.4%)
MRSE*, from Emmetropia, ± 1.00 D†	12/12 (100.0%)	46/47 (97.9%)	63/65 (96.9%)	59/59 (100.0%)	37/38 (97.4%)	29/30 (96.7%)	7/9 (77.8%)
MRSE*, from Emmetropia, ± 2.00 D†	12/12 (100.0%)	47/47 (100.0%)	65/65 (100.0%)	59/59 (100.0%)	38/38 (100.0%)	30/30 (100.0%)	9/9 (100.0%)
Loss of ≥ 2 lines BSCVA	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	1/62 (1.6%)	0/40 (0.0%)	0/30 (0.0%)	1/9 (11.1%)
Loss of > 2 lines BSCVA	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	0/62 (0.0%)	0/40 (0.0%)	0/30 (0.0%)	0/9 (0.0%)
BSCVA worse than 20/40	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	0/62 (0.0%)	0/40 (0.0%)	0/30 (0.0%)	0/9 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/12 (0.0%)	0/47 (0.0%)	0/66 (0.0%)	0/61 (0.0%)	0/38 (0.0%)	0/27 (0.0%)	0/8 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	0/62 (0.0%)	0/40 (0.0%)	0/30 (0.0%)	0/9 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	NA	NA	NA	NA	NA	NA	NA

N = Number of CRFs received with non-missing values at each visit.
* MRSE = Manifest Spherical Equivalent.
† For all eyes minus those treated for monovision
‡ For eyes treated for spherical myopia only.

4.2.3. STABILITY OF THE MANIFEST REFRACTION

Results for stability of the manifest refraction as determined by the manifest spherical equivalent refraction are presented for those eyes that had data at all scheduled follow-up visits during the study (the "consistent cohort"). Stability is defined as a change in the spherical equivalent manifest refraction of 1.00 diopter or less between successive visits at least 3 months apart for 95% of the treated eyes. Table 7 presents the results for those eyes treated for spherical myopia only. Table 8 presents the results for those eyes treated for astigmatic myopia.

Table 7
Stability of Manifest Refraction Spherical Equivalent (MRSE)
Eyes Treated for Spherical Myopia Only
Consistent Cohort (N = 93 Eyes)

Change in Refraction	Between 1 and 3 Months	Between 3 and 6 Months
Change of MRSE by ≤ 1.00 D		
n/N (%)	93/93 (100.0%)	91/93 (97.8%)
95% CI for %	(96.4%, 100.0%)	(94.3%, 99.9%)
Change of MRSE (Paired-Differences) in Diopters		
Mean	-0.050	-0.047
SD	0.322	0.307
95% CI for Mean	(-0.126, 0.027)	(-0.116, 0.022)

The 95% confidence interval was adjusted for the correlation between eyes.
This analysis used all eyes examined at 1, 3, and 6 months (consistent cohort).

Table 8
Stability of Manifest Refraction Spherical Equivalent (MRSE)
Eyes Treated for Astigmatic Myopia
Consistent Cohort (N = 256 Eyes)

Change in Refraction	Between 1 and 3 Months	Between 3 and 6 Months
Change of MRSE by ≤ 1.00 D		
n/N (%)	255/256 (99.6%)	255/256 (99.6%)
95% CI for %	(98.3%, 99.9%)	(98.3%, 99.9%)
Change of MRSE (Paired-Differences) in Diopters		
Mean	-0.134	-0.034
SD	0.344	0.292
95% CI for Mean	(-0.184, -0.084)	(-0.077, 0.010)

The 95% confidence interval was adjusted for the correlation between eyes.
This analysis used all eyes examined at 1, 3, and 6 months (consistent cohort).

For both treatment groups, the refraction was demonstrated to be stable by 3 months postoperative based upon the upper limit of the 95% confidence interval.

SECTION 5

SURGICAL PLANNING AND PROCEDURES

5.1. INTRODUCTION

LASIK is a procedure that combines the use of a microkeratome to create a lamellar corneal flap and the energy of the excimer laser to create a keratectomy in the corneal stroma of a shape designed to correct or reduce a specific refractive error. The intent is to properly focus visible light entering the eye to provide improved vision. It is essential that the refractive information upon which this surgical procedure is based is accurate and correctly transmitted to the laser. It is the sole responsibility of the surgeon to ensure that the information for each individual patient is accurate.

5.2. PRE-OPERATIVE PROCEDURES

A complete examination, including, but not limited to, cycloplegic evaluation, must be performed. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary. If there are any concerns regarding the appearance of the optic nerve, a threshold test of the visual field should be performed. Pre-operative corneal mapping (topography) is essential on all patients to exclude topographical abnormalities. Pachymetry must be performed to obtain a baseline central corneal thickness measurement to assure that the combination of the planned corneal flap thickness and the planned laser ablation will not approach closer than 250 microns to the corneal endothelium. Baseline evaluation of patients with myopia desiring refractive surgery should be performed within 30 days prior to LASIK surgery.

5.3. PERI-OPERATIVE PROCEDURES

5.3.1. ANESTHESIA

Extensive clinical experience has shown that LASIK excimer surgery is well tolerated and rarely causes significant pain. For this reason, systemic sedatives and injected local anesthetics are not required. Topical anesthesia applied just before insertion of the lid speculum should provide adequate control of pain during surgery. For those patients with a high degree of anxiety, appropriate medication may be given pre-operatively.

5.4. INTRA-OPERATIVE PROCEDURES

5.4.1. CREATING THE LAMELLAR FLAP WITH THE MICROKERATOME

The LASIK procedure requires the creation of a hinged corneal flap using a microkeratome prior to the laser ablation procedure. The microkeratome used to perform the LASIK procedure should be a legally marketed device in the United States. The physician should follow the specific procedures recommended in the operation manual supplied with the particular brand of microkeratome to be used. Once the corneal flap has been created, the laser ablation step may be performed.

5.4.2. PERFORMING THE LASER ABLATION

Following creation of the corneal flap, the laser ablation is then performed. The physician should refer to the User Guide supplied with the Bausch & Lomb TECHNOLAS 217A Excimer Laser System for proper operation and maintenance instructions. The physician must also have completed the appropriate technical and medical in-service training provided by the manufacturer prior to using the laser for actual surgery.

5.5. POST-OPERATIVE PROCEDURES

5.5.1. PATCHING AND MEDICATIONS

Following completion of the excimer laser surgery, appropriate topical medications and a corneal shield or firm patch should be applied to the eye. A combination steroid-antibiotic medication should be included at the time of patching. Some physicians may wish to omit steroids until the edge of the lamellar keratectomy has healed completely. The patient should be seen one day postoperatively to ensure that the corneal flap is properly in place.

5.5.2. ANALGESIA

The physician may wish to administer appropriate post-operative medications for the management of ocular pain. These may include the use of topical ophthalmic non-steroidal anti-inflammatory drugs (NSAIDs), as well as systemically administered medications for pain management.

5.5.3. HANDLING COMPLICATIONS

Following the LASIK procedure, the physician should carefully monitor the condition of the patient's cornea on a periodic basis with regard to the condition of the corneal flap and its location. Special attention should be given to the presence of any debris or epithelial cells in the interface between the flap and the underlying corneal stroma. The presence of such foreign material may require lifting of the flap to remove such debris and/or cells using appropriate surgical techniques. The use of topical ophthalmic steroid medications may be required to suppress any associated inflammation caused by debris or cells in the interface.

SECTION 6

BAUSCH & LOMB SURGICAL EXCIMER LASER SURGICAL PROCEDURE STEP-BY-STEP PROCEDURE

Prior to Surgery

Refer to the User Guide for the complete step-by-step procedure to be followed prior to commencement of the actual surgical procedure (laser set-up, fluence test, etc.).

Patient Training

1. This allows the patient to become familiar with fixating their eye, and with the light, noise and smell produced by the laser system during laser energy delivery. Explain to the patient that there is no pain associated with the laser beam striking the cornea. During patient training on a dry epithelium, no more than 20 pulses should be delivered.

2. Ask the patient to keep the operative eye focused on the red fixation light inside the laser downtube.

3. The patient's eye should be aligned according to the specific instructions in the User Guide.

Note: If the patient cannot fixate after two or three training attempts, the surgeon may want to consider rescheduling the patient for the procedure.

Note: The red aiming beam and the green focusing beam mark the image plane of the excimer beam. The desired vertical position is located where the red and green beams overlap and appear as one spot.

4. Once the patient has demonstrated adequate fixation during the training session, the LASIK procedure may begin.

Microkeratome Surgery

The physician should perform the lamellar keratectomy to create the corneal flap according to the instructions provide with the microkeratome. Once the corneal flap has been created, the laser ablation portion of the procedure may be started.

Laser Surgery

1. Verify that the desired diopters of correction have been properly entered into the TECHNOLAS 217A Excimer Laser System and arm the laser.

2. Reposition the patient's eye under the laser. Ensure that the corneal flap is properly reflected back onto the bulbar conjunctiva and is not in a position to be impacted by the laser beam.

3. Instruct the patient to continue fixating on the red fixation light located in the laser downtube. On the anterior surface of the corneal stroma, the aiming beams should appear as one spot centered over the pupil and the red and green beams should overlap one another. Alignment of the eye with the aiming beams may be facilitated by reducing external illumination.

4. Press the footswitch until the laser stops firing. The total number of laser pulses for the desired refractive correction should be delivered in one continuous application if at all possible.

Note: The delivery of laser energy may be interrupted at any time by lifting the foot off the footswitch.

5. The physician should observe the procedure through the operating microscope. While the laser is firing, the physician should closely observe the fixation of the patient's eye. If the patient's eye moves during the procedure, firing of the laser should be stopped. The patient should be instructed to refixate and the treatment resumed. The laser system will keep track of how any pulses have been delivered and how many are remaining. During laser energy delivery, the physician should concentrate on the alignment beams. The physician should not be distracted by watching the laser energy impacting the cornea.

6. Once the laser ablation is completed, the corneal flap should be gently reflected back on to the corneal bed and properly positioned using appropriate instruments and balanced salt solution, as needed. The cornea should be examined carefully for the presence of any debris or epithelial cells in the interface, and, if the interface is clear, the flap should be allowed to adhere for a few minutes before proceeding.

Postoperative

1. Remove the lid speculum.

2. Apply one (1) drop of Voltaren ophthalmic solution.

3. Apply one or two drops of an appropriate ophthalmic steroid-antibiotic combination.

4. Use of a clear shield, a metal shield, or a patch is recommended for the first 24 hours postoperative to prevent the corneal flap from being displaced. If the flap appears to be firmly adherent to the underlying stroma at 24 hours postoperative, the shield may be removed at the physician's discretion.

5. Most patients will not experience significant post-surgical pain following the LASIK procedure. However, if needed, post-treatment pain medication may be prescribed at the physician's discretion. In reference to post-treatment medications during both the immediate and post-treatment period and for the first several weeks after the treatment, the physician should refer to the Clinical Results section of this document and the existing peer review literature to determine the appropriate course of action.

Retreatment

A small percentage of LASIK patients may experience undercorrection of the refractive error. This may be corrected by subjecting the eye to a retreatment. The retreatment procedure used is similar to that for the original (primary) surgery, except that only the amount of the remaining uncorrected refractive error is programmed into the laser's computer. All other details of the surgery should essentially remain the same as for the primary surgery. The decision whether to lift the original corneal flap or to create a new flap with the microkeratome must be made using the physician's best medical judgment.

SECTION 7

EMERGENCY OFF

If a system emergency situation arises, press the Emergency-Off Switch. This switch turns off the complete laser system. It is located on the front side below the computer monitor in the TECHNOLAS 217A. Pressing the emergency-off switch is the fastest possible way to completely switch off the laser system.

FACTS YOU NEED TO KNOW ABOUT LASER IN SITU KERATOMILEUSIS (LASIK) SURGERY FOR THE CORRECTION OF -1.00 TO -7.00 DIOPTERS OF NEARSIGHTEDNESS AND LESS THAN 3.00 DIOPTERS OF ASTIGMATISM WITH THE BAUSCH AND LOMB SURGICAL TECHNOLAS® 217A EXCIMER LASER SYSTEM

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its content with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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INTRODUCTION

This booklet contains information to help you decide whether or not to have Laser in situ Keratomileusis (LASIK) laser surgery for the correction of nearsightedness. Glasses, contact lenses, or the refractive surgical procedures known as photorefractive keratectomy (PRK) and radial keratotomy (RK) also correct nearsightedness. LASIK, using the Bausch and Lomb Surgical excimer laser system, is a completely different type of surgery than RK, but somewhat similar to PRK.

If you are nearsighted in both eyes, it may be necessary to have both eyes treated with LASIK. Sometimes, it is better to have LASIK done on only one eye. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, such as military pilots, have vision requirements that RK, PRK, and LASIK presently cannot meet.

HOW THE EYE FUNCTIONS

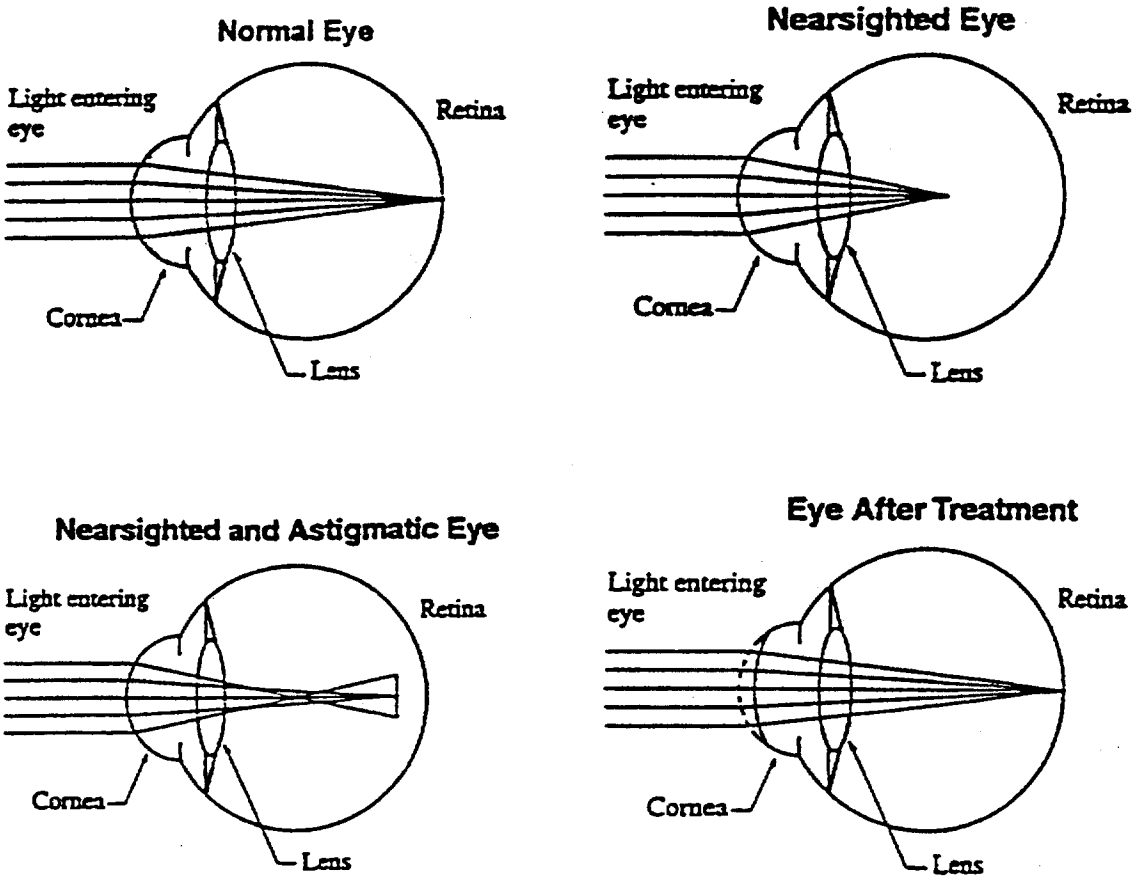
Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into electrical signals and sends them to the brain. If your eye is out of focus, what you see is blurred.

The cornea at the front of the eye bends the light toward your retina. The clear tissue of the cornea is responsible for two-thirds of the focusing power of the eye. The lens within the eye finishes the job of focusing the light onto your retina.

Focusing with Your Eye

The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

The shape of the cornea determines the focusing power of the eye. The more sharply curved the cornea, the more that light rays are bent. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is irregularly shaped (like a football rather than a basketball), it is called astigmatic.



Checking Your Focus

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

The Nearsighted Eye

One in four people in North America are nearsighted. They see near objects clearly, but distant objects are blurry. Light rays focus in front of the retina instead of directly on it. Nearsightedness tends to run in families. It usually starts in childhood and stabilizes in the late teens or early adulthood. Nearsightedness can be corrected by glasses, contact lenses or refractive surgery.

Glasses and contact lenses can be adjusted if vision changes over time. Changes due to refractive surgery are usually permanent and cannot be undone if vision or focus changes. If your vision changes or the initial surgery is not completely successful (which occurred in 0.3% of the cases treated in the Bausch and Lomb Surgical clinical study), additional treatments may be performed

to try to improve your results. In the Bausch and Lomb Surgical study, there were no eyes that required a re-treatment for myopia correction.

WHAT IS LASER IN SITU KERATOMILEUSIS (LASIK)?

LASIK is a surgical treatment for nearsightedness. A small surgical instrument called a microkeratome, which is much like a carpenter's plane, is used to make a very thin flap of tissue on the cornea (the clear part on the front of the eye). This flap is then folded out of the way, and an excimer laser is used to flatten the front surface of the cornea below the flap. The laser removes small amounts of tissue with ultraviolet light. After the laser treatment is finished, the corneal flap is placed back into its original position on the cornea. This is different from RK. In RK, a surgical knife is used to make deep cuts around the center of the cornea.

An excimer laser is a machine that produces and aims a powerful beam of ultraviolet light. The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. Each pulse removes a microscopic amount of tissue from the surface of the cornea. It produces little heat and leaves the tissue beneath unchanged.

LASIK surgery is performed on one eye at a time. The second eye can be treated if all goes well with the first eye. Laser surgery on the second eye can usually be done on the same day as the first eye, or may be done later, depending on your doctor's evaluation of your particular case.

In the clinical study of the TECHNOLAS 217A Excimer Laser System, 87.3% of all treated eyes could see 20/20 or better without glasses after a single LASIK procedure, and 99.7% could see 20/40 or better. Although vision without glasses improved for all eyes, some patients still needed glasses or contact lenses after LASIK. LASIK to correct distance vision does not eliminate the need for reading glasses. It is possible that you may need reading glasses after laser surgery even if you did NOT wear them before.

Benefits

LASIK surgery, performed with the TECHNOLAS 217A Excimer Laser System, is effective in reducing or eliminating nearsightedness of -1.00 to -7.00 diopters with astigmatism less than 3.00 diopters.

LASIK may reduce overall nearsightedness while reducing or eliminating dependency on contact lenses or glasses.

LASIK surgery, performed with the TECHNOLAS 217A Excimer Laser System, is a reasonably safe and effective alternate way to correct nearsightedness.

Risks

To get the best possible vision, you may need to have additional LASIK surgery if your initial surgery results are not satisfactory.

In addition, it is possible that LASIK surgery may result in a decrease in your best corrected vision compared to before you had the surgery.

LASIK surgery may cause visual problems or symptoms that you did not have before the surgery, or may make such pre-existing problems or symptoms worse following the surgery.

There is a risk of infection of the cornea or other parts of the eye, as a result of the LASIK surgery, due to removal of tissue from the front surface of the eye as part of the procedure.

There is a risk of perforation (cutting completely through the cornea) of the eye during the microkeratome portion of the surgery to create the corneal flap, which could lead to loss of fluid from inside the eye, cataract formation, and infection of the eye.

During the first week following surgery

- Pain and discomfort may last for up to 7 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You may be sensitive to bright lights.

For the first week to one month following surgery

- The pressure in your eye may increase due to use of anti-inflammatory medications. When you stop the medication or use other drug therapy, the pressure goes back to normal.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze disappears over time. Some patients continue to experience haze up to 6 months after the surgery.

3 and 6 months after surgery

The Bausch and Lomb Surgical clinical studies showed that for the following problems more than 1% of patients reported that these problems were worse at 3 or 6 months *after the surgery,* than before the surgery.

EYES TREATED WITHOUT ASTIGMATISM

	3 Months N=102/105			6 Months		
	Better	No Change	Worse	Better	No Change	Worse
Dryness	17.3%	55.8%	26.9% 27	21.6%	52.3%	26.1%
Halos	5.8%	73.1%	21.2%	4.5%	76.1%	19.3%
Fluctuations of vision	6.7%	75.0%	18.3%	6.8%	73.9%	19.3%
Variation of vision in dim light	14.4%	68.3%	17.3%	14.8%	67.0%	18.2%
Light sensitivity	23.1%	59.6%	17.3%	26.1%	58.0%	15.9%
Blurred vision	8.7%	74.0%	17.3%	11.4%	73.9%	14.8%
Night driving vision	19.2%	61.5%	19.2%	22.7%	63.6%	13.6%
Glare	11.5%	71.2%	17.3%	10.2%	77.3%	12.5%
Variation of vision in bright light	5.8%	86.5%	7.7%	6.8%	86.4%	6.8%
Redness	16.3%	74.0%	9.6%	20.5%	73.9%	5.7%
Variation of vision in normal light	0.0%	95.2%	4.8%	1.1%	93.2%	5.7%
Headaches	13.5%	81.7%	4.8%	12.5%	83.0%	4.5%
Gritty feeling	11.5%	80.8%	7.7%	18.2%	78.4%	3.4%
Tearing	7.7%	86.5%	5.8%	9.1%	88.6%	2.3%
Burning	5.8%	88.5%	5.8%	6.8%	90.9%	2.3%
Ghost images	1.0%	97.1%	1.9%	1.1%	96.6%	2.3%
Double vision	2.9%	94.2%	2.9%	3.4%	95.5%	1.1%
Pain	1.9%	95.2%	2.9%	1.1%	98.9%	0.0%

EYES TREATED WITH ASTIGMATISM

	3 Months N=260/271			6 Months		
	Better	No Change	Worse	Better	No Change	Worse
Halos	4.5%	68.8%	26.7%	6.5%	75.4%	18.1%
Dryness	20.7%	61.3%	18.0% 47	30.4%	55.8%	13.8%
Fluctuations of vision	6.4%	78.2%	15.4%	7.7%	79.2%	13.1%
Night driving vision	20.7%	67.7%	11.7%	22.7%	66.5%	10.8%
Variation of vision in dim light	14.3%	71.8%	13.9%	18.1%	71.5%	10.4%
Glare	10.2%	74.4%	15.4%	11.2%	79.2%	9.6%
Light sensitivity	19.9%	66.5%	13.5%	21.9%	68.8%	9.2%
Blurred vision	11.3%	74.4%	14.3%	15.4%	75.8%	8.8%
Gritty feeling	11.3%	81.6%	7.1%	11.2%	81.9%	6.9%
Redness	18.4%	73.3%	8.3%	20.0%	73.5%	6.5%
Variation of vision in bright light	11.7%	80.5%	7.9%	9.6%	84.2%	6.2%
Variation of vision in normal light	4.1%	84.2%	11.7%	5.0%	89.2%	5.8%
Burning	11.3%	78.6%	10.2%	13.8%	81.2%	5.0%
Double vision	1.1%	97.0%	1.9%	2.7%	94.2%	3.1%
Pain	5.3%	87.6%	7.1%	5.8%	91.5%	2.7%
Ghost images	1.1%	96.2%	2.6%	1.2%	96.5%	2.3%
Tearing	13.2%	83.5%	3.4%	13.5%	84.6%	1.9%
Headaches	19.2%	77.4%	3.4%	20.0%	78.8%	1.2%

During the clinical trial of LASIK, less than 1% of **patients** reported the following effects of their LASIK surgery at 6 months after the surgery:

Itching, eyestrain, mattering of the eyes, swelling of the eyelids, floating spots or specks in their vision, and problems with night vision.

During the Bausch and Lomb Surgical clinical trials, **doctors** reported the following complications:

Early complications (during the first few weeks after LASIK)

Corneal swelling; cloudy vision; defect in the outer layer of the cornea; displacement, wrinkling, or folding of the corneal flap; double vision; presence of cells under the corneal flap; and inflammation of the cornea. The normal healing process following LASIK surgery can result in these complications.

Medium-term complications (3 months after surgery)

Cloudy vision; defect in the outer layer of the cornea; wrinkling of the flap, double vision; and presence of cells under the corneal flap. Generally, these complications decline over time.

Long-term complications (6 months after surgery)

These occurred in more than 1% of patients who were in the Bausch and Lomb Surgical clinical trials. These complications continued even after early discomfort ended:

- Cells in the space between the flap and the corneal tissue below the flap. This occurred in 1.1% of patients.

The study also showed that certain vision-threatening events happened, 1.0% or less of the time, at 6 months after LASIK surgery:

- Farsightedness caused by the surgery
- Folds or lines in the corneal flap
- Cells growing under the corneal flap causing significant vision loss

Contraindications

You should **NOT** have LASIK surgery if:

- You have collagen, vascular, autoimmune, or immunodeficiency disease (e.g., lupus or AIDS).
- You are pregnant or nursing.

- You show signs of keratoconus (a corneal disease) or have any other condition that causes thinning of your cornea.
- You are taking Accutane (isotretinoin) for acne treatment or Cordarone (amiodarone hydrochloride) for controlling normal heart rhythm.

Warnings

Discuss with your doctor if:

- You have a systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status.
- You have had *Herpes simplex* or *Herpes* zoster infections.

Precautions

The safety and effectiveness of the TECHNOLAS 217A Excimer Laser System have **NOT** been established:

- In patients with unstable or worsening nearsightedness or astigmatism
- In patients with diseased or abnormal corneas (scars, infections, etc.).
- In patients with previous surgery or injury to the center of the cornea where LASIK will be performed.
- In patients with abnormal blood vessels within 1.0 mm of the center of the eye where LASIK will be performed.
- In patients under 21 years of age.
- In patients taking hormone replacement therapy or antihistamines.
- In patients taking sumatripin (Imitrex) for migraine headaches.
- In patients with a history of glaucoma.
- In patients with refractive treatments >7 D of nearsightedness and ≥ 3.0D of astigmatism.
- In patients with corneas too thin for the procedure to be completed.
- To avoid corneal ectasia, the posterior 250 micons (μm) of corneal stroma should not be violated by the laser or the microkeratome.
- The effects of LASIK on visual performance under poor lighting conditions have not been determined. It is possible, following LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes.
- Over the longer term (more than 6 months after surgery).
- In patients with a history of keloid formation.
- In patients with a tendency to form scars.
- No safety and effectiveness data exist for LASIK treatments above 7.00 D of nearsightedness or for more than 3.00 D of astigmatism and there is insufficient data for LASIK treatment of astigmatism above 3.00 D with the TECHNOLAS 217A Excimer Laser System.

Although it has not been studied, you may find it more difficult than usual to see in poor lighting conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

ARE YOU A GOOD CANDIDATE FOR LASIK?

If you are considering LASIK, you must:

- Be 21 years of age or older.
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease.
- Have nearsightedness within the range of treatment: -1.00 to -7.00 diopters of nearsightedness with less than 3.00 diopters of astigmatism.
- Have written proof that the change in your vision is one-half diopter or less per year for at least one year before your pre-surgery exam.
- Be fully informed about the risks and benefits of LASIK as compared to other treatments for nearsightedness.
- Be able to lie flat without difficulty.
- Be able to keep your eye accurately on the red fixation light during the entire LASIK procedure.
- Be willing to sign an Informed Consent Form provided by your eye care professional.
- Be able to tolerate eye drops to numb your eye.

WHAT YOU NEED TO KNOW ABOUT THE SURGERY

Before the Surgery

If you are interested in LASIK, you will need a pre-surgical examination to determine if your eye is healthy and suitable for LASIK. The exam includes a physical and eye history. Both eyes will be checked. Your cornea will be mapped by computer to determine if it is smooth and properly shaped.

WARNING: If you wear contact lenses, the doctor will ask you to stop wearing them two to four weeks before your exam. Failure to do this may produce poor surgical results.

Before surgery, talk to your doctor about any medicine you take. Also discuss whether or not you should eat and drink just before surgery. You should arrange to have someone drive you home after surgery and to your next doctor's appointment. You should not drive until your doctor gives you permission.

The Day of Surgery

Before the actual surgery, you will be given the opportunity to hear the sounds the laser makes so that you will be prepared for the noise during surgery. You will be given some numbing drops in the eye that will be treated. When you go into the room that contains the laser system, you will see a large machine that has a computer screen, a surgeon's chair and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser's microscope and the ceiling. Your eye may be numbed with more drops. The eye not having surgery may be covered with a temporary shield.

The surgery takes about 10-20 minutes overall. The use of the laser, however, lasts only about 15 to 40 seconds. The doctor will place a small spring-like device between your eyelids to hold them open.

When the surgery begins, the surgeon will use a small instrument to create a thin flap of corneal tissue that is folded away from the cornea. The doctor will then reposition your head under the microscope. You will be asked to look directly at the red light. Try to keep both eyes open without squinting. This makes it easier to keep looking at the red light. You will then hear the noise the laser makes when it is delivering the laser energy.

WARNING: It is very important that you keep looking directly at the red light, even if the light fades or dims. Your results depend on how well you look directly at this red light throughout the treatment.

Immediately after the surgery

After the surgery, your doctor will put some medicated drops or ointment into your eye. Your doctor may apply a patch or protective shield to your eye for protection and comfort.

Numbing drops make the surgery painless. When these drops wear off, your eye may hurt for a day or two. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not remove the patch or shield until instructed to do so. Do not rub or touch your treated eye for the first one to seven days after surgery.

First days after surgery

The patch or shield is usually removed the next day. You may be mildly sensitive to light and glare. Wearing sunglasses may make you more comfortable. You may also have the feeling that something is in your eye. This happens while the outer layer of your cornea is healing.

Your vision should stabilize within a few weeks. Some patients report small changes in vision such as improvement or worsening. These changes may occur up to six months or more after surgery.

You may see a haze or cloudiness in the cornea following surgery. It usually does not affect your vision. This haze tends to decrease over time. It usually disappears completely by 12 to 24 months after the surgery.

Use any prescribed drops and lubricants as directed by your doctor. Your surgical results depend on carefully following your doctor's directions.

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correcting nearsightedness?
- Will I have to limit my activities after the treatment? If yes, for how long?
- What are the benefits of LASIK for my level of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If LASIK does not correct my vision, could my vision be worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after LASIK?
- How is LASIK likely to affect my need to use glasses or contact lenses as I get older?
- Will my cornea heal differently if I injure it after having LASIK?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK surgery on my other eye?
- What vision problems will I experience if I have LASIK only in one eye?

Discuss the cost of surgery and follow-up care with your doctor. Most health insurance policies do not cover excimer laser treatment for vision correction.

SUMMARY OF IMPORTANT INFORMATION

- LASIK is permanent. Once performed, it is not reversible.
- LASIK does **NOT** eliminate the need for reading glasses, even if you have never worn them.
- Your vision must be stable for at least one year before LASIK surgery. You will need written proof that your nearsightedness has not changed by more than 0.50 diopters.
- Pregnant and nursing women should wait to have the surgery.
- You would not be a good candidate if you have any medical condition that makes wound healing difficult.
- The LASIK treatment may cause you discomfort.
- The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks, before you agree to the treatment.
- LASIK is not a laser version of radial keratotomy (RK). These operations are completely different from each other.

- Some alternatives to LASIK include glasses, contact lenses, photorefractive keratectomy (PRK), and RK.
- Some jobs, such as military pilots, have vision requirements that RK, PRK, or LASIK do not presently meet.

Before considering LASIK you should:

Have a complete eye examination.

Talk with one or more eye care professionals about the potential benefits of LASIK and the complications, risks and time required for healing.

GLOSSARY OF TERMS

astigmatism: Refractive error which prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the various meridians of the eye.

cornea: Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of an eye's optical focusing power.

diopter: Unit of measurement of optical strength or refractive power of lenses.

excimer laser: A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to be more accurately focused on the retina.

farsightedness/ hyperopia: Condition in which the eye is "under-powered", so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina". Corrected with additional optical power, supplied by a "plus" lens or by additional use of the eye's own focusing ability.

halos: Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling).

keratoconus: Hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.

LASIK: An acronym for "laser in situ keratomileusis". This is a surgical procedure in which a very thin flap of tissue on the clear front part of the eye (cornea) is made using a small surgical instrument called a microkeratome, which is much like a carpenter's plane. The flap is then folded out of the way and an excimer laser is used to flatten the front surface of the cornea below the flap.

lens: A transparent, colorless body located in the front third of the eyeball, between the aqueous and the vitreous, the function of which is to help bring rays of light to focus on the retina.

nearsightedness/ myopia: "Overpowered" eye in which parallel light rays from a distant object are brought to focus in front of the retina. Requires "minus" lens correction to "weaken" the eye optically and permit clear distance vision.

pupil: The opening at the center of the iris of the eye for the transmission of light, which varies in diameter depending upon the brightness of the light coming into the eye.

PRK: An acronym for "photorefractive keratectomy". This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed by the excimer laser in a predetermined manner to re-shape the cornea to correct refractive errors of the eye.

refractive surgery: Several different procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.

retina: The thin lining of the back of the eye that converts images from the eye's optical system into electrical impulses sent to the brain.

RK An acronym for "radial keratotomy". This is a surgical procedure in which a predetermined number of radial cuts are made in the periphery of the cornea. This allows the central cornea to flatten and thereby reduces nearsightedness.

PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

Name:
Address:

Telephone Number:

LASIK DOCTOR

Name:
Address:

Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:

Telephone Number:

LASER MANUFACTURER

Technolas GmbH
(A Bausch & Lomb Surgical Company)
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